



THE ASSOCIATION FOR

**DRESSINGS & SAUCES**

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July 15, 2005

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Docket No. 1998N-0359; Program Priorities in  
the Center for Food Safety and Applied Nutrition

The Association for Dressings and Sauces (ADS) appreciates the opportunity to provide input regarding the Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition's (CFSAN) program priorities for the fiscal year 2006, as requested in the May 20 *Federal Register (FR)* notice (70 *FR* 29328). ADS is an international association of manufacturers of dressings for salads, mayonnaise, mustard and specialty sauces and their suppliers. A list of our members is enclosed.

We applaud the Agency for continuing to provide interested parties the opportunity to participate in the CFSAN priority-setting process. ADS has offered the insight of the dressings and sauces industry on such priorities since the Agency began this initiative in 1998. (See ADS' most recent comments dated August 5, 2004.) We continue to agree one of the Center's primary goals is ensuring food defense and security. FDA previously issued interim final rules regarding facility registration and prior notice of imported foods and a final rule regarding administrative detention as mandated by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act"). In addition, the Agency recently issued a final rule regarding records establishment and maintenance. ADS staff attended one of FDA's recent outreach meetings on this rule. It is evident from the questions received during the session that there is possible confusion regarding the requirements of the rule and some issues still need to be addressed, e.g., records establishment and maintenance for non-transporters as it relates to the identity of the immediate previous source and lot code identification for vertically integrated companies. We urge the Agency to quickly issue the Question and Answer document that has been developed on this rule so areas of confusion can be addressed, allowing the food industry to more fully understand the requirements.

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A priority of equal importance to food security is food safety. As part of the on-going efforts regarding food safety, the coordination on foodborne disease outbreaks should be a priority. Too often a food is wrongly implicated in a foodborne disease outbreak because of the lack of coordination among state and Federal agencies investigating the outbreak. Accurate and timely information regarding such outbreaks is in the best interest of all involved, and most importantly, the consumer.

However, as our earlier comments have stated, there are other key functions in which the Agency should focus its efforts, specifically the continued maintenance and administration of the food standards program, national uniformity, promoting international harmonization, and preventing economic fraud. We continue to strongly believe these areas deserve CFSAN's attention and a place on the "A" list of priorities. Detailed comments follow.

#### Maintenance and Administration of the Food Standards Program

It is evident from comments received on the Agency's Advance Notice of Proposed Rulemaking (ANPRM) on food standards (60 *FR* 67492; December 29, 1995) that a number of existing standards presently serve as barriers to the utilization of new technologies and required ingredients to improve existing products. As a result, petitions have been prepared and filed in several important product categories to affect needed amendments to recognize the advances in food technology and the need for flexibility.

We applaud the Agency's recent proposed rule jointly issued by the United States Department of Agriculture's Food Safety and Inspection Service (FSIS) to establish general principles for establishing, revising or eliminating a food standard. The proposed rule preserves food standards of identity, which both industry and consumer groups recognize to be beneficial, and responds to concerns about the complexity and inflexibility of outmoded food standards. However, the proposal does not address the current resources allocated to foods standards reform and enforcement by FDA and FSIS. Additionally, the proposed rule retains subpart (a) of FDA's existing food standard procedure, 21 CFR Section 130.5. This means that petitions to eliminate, establish or revise a food standard are still subject to the procedures contained in 21 CFR part 10. As history shows, the current process can take an extremely long time, where petitions fall into an administrative black hole, and it is unclear whether the proposed rule will accelerate this process. The proposed rule is also silent on how the agencies plan to address petitions previously submitted.

On January 13, 1998, ADS submitted a Citizen Petition that reflected the consensus reached within the dressings industry on how FDA should proceed in implementing the ANPRM with respect to the standards of identity of interest to this industry. The Association requested that the Commissioner of Food and Drugs initiate rulemaking to (1) repeal the standard of identity for French dressing (21 CFR 169.15), and (2) revise, simplify and modernize the standards of identity for mayonnaise and salad dressing (21 CFR 169.140, 169.150). ADS' efforts to update or repeal obsolete standards should be supported by FDA, but almost eight years later, no action has been taken by the Agency, despite the fact that the Association provided the

necessary information to move forward. ADS continues to discuss with FDA personnel other means of expediting the petition, but no FDA action has been forthcoming. At a minimum, we believe the Agency should provide annual updates on standards petitions so that petitioners are aware of the status and can advise their constituents, accordingly. We are hopeful the recent proposed rule mentioned previously in these comments will offer relief in the standards area, and we plan to submit further comments on this vital issue in response to the proposed rule.

#### National Uniformity

National uniformity between Federal and state agencies also should be an "A" list priority for CFSAN in FY 2005. There should be a single set of food safety regulations interpreted in the same way by both Federal and state regulators. A uniform set of regulations and interpretations will eliminate the confusion that currently exists as industry strives for compliance at the local and Federal levels. As an example, the Association is attempting to resolve conflicting state interpretations of the Federal acidified foods regulations. The paper, "Microbiological Safety of Mayonnaise, Salad Dressings and Sauces Produced in the United States: A Review," was developed by Dr. Richard Smittle to assist in this process, which was published in the *Journal of Food Protection*. ADS staff previously contacted FDA personnel to obtain direction on how to distribute the paper and related backgrounder to process authorities and state and Federal regulators to educate such persons on the safety of industry's products, and therefore, avoid conflicting interpretations. In discussions with FDA personnel regarding this issue, the Agency acknowledges the conflicts and reasons for the confusion, but ADS' offer to provide assistance in this area has not been utilized, and yet, no other FDA action is taken.

Mostly recently, the Association sponsored research to reaffirm the safety of shelf stable, dairy-based, pourable salad dressings. This study demonstrates that the death rate of *Salmonella*, *E. coli* O157:H7, and *L. monocytogenes* in ten commercially manufactured shelf stable, pourable full fat and reduced fat ranch and blue cheese salad dressings stored at 25°C is rapid. The study is being submitted for publication to the *Journal of Food Protection*. It would be helpful if ADS had a means to share this study with appropriate individuals within FDA. As such, ADS believes the Agency should establish a means for industry to communicate safety information to such FDA personnel as inspectors and process authorities to further their knowledge on the safety of industry-specific products and to assist in moving toward national uniformity and standard interpretation.

#### Promotion of International Harmonization

The modernization and maintenance of United States (U.S.) food standards and national uniformity of regulations, including those pertaining to food safety, are also important as the U.S. participates in the Codex Alimentarius process. In order for the U.S. to be an effective player within Codex, U.S. standards must be science-based, reflective of current practices, and be national in scope, which will give the U.S. a strong basis for negotiation. It is, therefore, critical that the U.S. positions on several Codex standards be thoroughly reviewed by industry so current industry practices are reflected. We, therefore, encourage more timely

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communications between FDA and industry. In the increasingly global marketplace, the promotion of international harmonization is imperative, and the U.S. should take a leadership role in the Codex process. Thus, it is crucial that U.S. positions be shared with other countries in a timely manner so meaningful discussions can occur during Codex committee meetings.

Prevention of Economic Fraud

Lastly, economic fraud should be a CFSAN priority because of its importance to both consumers and industry. FDA must continue to pursue and prosecute fraudulent activities. Individuals and companies engaged in such activities are just as likely to have little regard for the welfare and safety of the public and should not be allowed to operate. FDA's efforts in this regard should be to enforce the existing statutory provisions.

In conclusion, ADS appreciates the opportunity to provide comments on CFSAN's fiscal year 2006 priorities. While we agree that food defense and security and food safety should continue to be CFSAN's top priorities, the Agency is also responsible for other important functions as outlined in these comments. Thus, we encourage the Agency to balance its resources accordingly.

Sincerely,

A handwritten signature in black ink that reads "Pamela A Chumley". The signature is written in a cursive style with a large, sweeping initial "P".

Pamela A. Chumley  
Executive Director

Enclosures



# ***The Association for Dressings & Sauces***

## ***Manufacturer Member List***



Annie's Naturals	T. Marzetti Company
Baldwin Richardson Foods Co.	Mega Alimentos, S.A. de C.V.
Bear Creek Country Kitchens	Morehouse Foods, Inc.
Cains Foods, Inc.	Mrs. Clark's Foods, Inc.
Cargill Custom Dressings	Olds Products Company
The Carriage House Companies, Inc.	Ott Food Products Company
Chelten House Products, Inc.	Pacific Harvest Products, Inc.
Clements Foods Company	Piknik Products Company, Inc.
The Clorox Company	Plochman, Inc.
Creative Foods, LLC	Q & B Foods, Inc.
Dean National Brand Group	Reily Foods Company
Fish House Foods, Inc.	Renée's Gourmet Foods, Inc.
Food Specialties Company, Inc.	Safeway, Inc.
Furst-McNess Company	Salad Soulmates, Inc.
M.A. Gedney Company	Sara Lee Dressings & Sauces
Gold Pure Food Products Company, Inc.	The C.F. Sauer Company
Golden State Foods	Seaforth Creamery, Inc.
Green Garden Food Products, Inc.	Seminole Foods
Griffin Foods Company	Sisters and Brothers, Inc.
Hartville Kitchen Foods, Inc.	Silver Spring Gardens, Inc.
Ken's Foods, Inc.	E.D. Smith
Kerry, Inc.	Thor-Shackel Horseradish Company
Kimlan Foods Company, Inc.	Tone Products, Inc.
Kraft Foods, Inc.	Tulkoff Food Products, Inc.
The Kroger Co.	Unilever Foods
Litehouse, Inc.	Ventura Foods, LLC
Louisiana Fish Fry Products	Wing's Food Products
	The Wizard's Cauldron, LTD.



# ***The Association for Dressings & Sauces***

## ***Supplier Member List***



A & B Process Systems  
Accurate Ingredients, Inc.  
Admix, Inc.  
AG Processing, Inc.  
Ajinomoto Food Ingredients, LLC  
Alcan Packaging  
Archer Daniels Midland Company  
Arla Food Ingredients, Inc.  
Aromatic, Inc.  
AVEBE America, Inc.  
Baltimore Spice, Inc.  
Bell Flavors & Fragrances  
Bender-Goodman Company, Inc.  
Brown Produce Company  
Butter Buds Food Ingredients  
CHS, Inc.  
CP Kelco  
Camerican International, Inc.  
Cargill, Inc.  
Centrus International, Inc.  
Chemicolloid Laboratories, Inc.  
Chianti Cheese Company  
Chr. Hansen, Inc.  
Citrus and Allied Essences, Ltd.  
Commercial Creamery Company  
ConAgra Foods  
Constar International, Inc.  
Continental Custom Ingredients, Inc.  
H.S. Crocker Company, Inc.  
Cryovac Sealed Air Corporation  
Culinary Farms  
Cutler Egg Products, Inc.  
DSM Food Specialties  
Danisco USA, Inc.  
Demeter (1993), Inc.  
G.S. Dunn & Company, Ltd.  
Edlong Dairy Flavors  
Elite Spice, Inc.  
Enercon Industries Corporation

Excelon International  
FMC Biopolymers  
Fabri-Kal Corporation  
Fleischmann's Vinegar Co., Inc.  
Frencharoma Imports Company, Inc.  
Ful-Flav-R Food Products Co., Inc.  
GNT USA, Inc.  
Gerstenberg-Schröder North America  
GRAFCO PET Packaging Technologies  
Grain Millers, Inc.  
Grain Processing Corporation  
Grande Custom Ingredients Group  
Gum Technology Corporation  
G.C. Hahn & Company  
Haliburton International Corporation  
T. Hasegawa Flavors  
Hassia USA, Inc.  
ISP Food Ingredients  
Ingredients Solutions, Inc.  
Jeneil Biotech, Inc.  
JohnsonDiversey  
Jungbunzlauer, Inc.  
Kalsec, Inc.  
Kerr Group, Inc.  
Kerry Seasonings  
Leone Industries  
Liquid Container/Plaxicon  
Mastertaste  
Michael Foods, Inc.  
Mizkan Americas, Inc.  
Montana Specialty Mills, LLC  
Morton Salt  
Mr. Chips, Inc.  
National Starch Food Innovation  
Neogen Corporation  
M.G. Newell Corporation  
Nikken Foods Company  
Phoenix Closures, Inc.  
Presco Food Seasonings, Inc.

Pretium Packaging  
Printpack, Inc.  
Progressive Plastics, Inc.  
Provesta Flavor Ingredients  
PURAC America  
Quest International  
Red Arrow Products Co. LLC  
Rex Wine Vinegar Company  
Ring Container Technologies  
Ripon Pickle Company, Inc.  
Rodem, Inc.  
Roquefort Association, Inc.  
Sakai Spice (Canada) Corporation  
Saputo Cheese USA, Inc.  
Sartori Food Corporation  
Scott Turbon® Mixer, Inc.  
SILLIKER, Inc.  
Silva International, Inc.  
Smyth Companies, Inc.  
Sokol and Company  
Sonstegard Foods Company  
Sparboe Foods  
Spartech Corporation  
SunOpta Ingredients  
SupHerb Farms  
Tate & Lyle  
TIC Gums, Inc.  
Todhunter Foods & Monarch Wine Co.  
TricorBraun  
Univ. of NE, Food Processing Center  
Upstate Farms  
Valley Sun Products of California  
Van Drunen Farms  
Vegetable Juices, Inc.  
Weatherchem Corporation  
D.D. Williamson & Co., Inc.  
Winona Foods  
Winpak, Inc.  
Wisconsin Spice, Inc.